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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,742	09/25/2006	Zhi Hong	6319-4016	9432

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

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02/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,742	HONG ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/8/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Response Dated December 8, 2008

1. Claims 1-25 are pending. An action on the merits of claims 1-25 is contained herein below.

2. The rejection of claims 2-3 and 6-7 under 35 U.S.C. 112, second paragraph, has been withdrawn.

3. The rejection of claims 1, 5, 9-18 and 24-25 under 35 U.S.C. 102(e) as being anticipated by Bhat et al. US 6,777,395 (Bhat) has been withdrawn in view of applicant's arguments dated December 8, 2008.

4. The rejection of claims 2-4, 6-8 and 19-23 under 35 U.S.C. 103(a) as being unpatentable over Bhat in view of Erion et al. US 7,205,404 (Erion) has been withdrawn in view of applicant's arguments dated December 8, 2008.

Claim Objections

5. Claims 2-4, 6-9 and 19-23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Formula I and Formula II depict "complete" chemical structures. The compound of Formula II does not allow for any modifications, and the compounds of Formula I only vary at position X. Prodrugs are not embraced by Formulae I and II.

In claim 9, the text "wherein X comprises a nitrogen atom" is broader in scope than the definition for X set forth in claim 5.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2, 5-6, 9-21 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMADOSSI et al. WO 01/90121 (SOMMADOSSI).

Claims 1-2 are drawn to a compound according to Formula I or Formula 2. Claims 5-6 and 9-12 are drawn to a pharmaceutical composition comprising a compound according to Formula I or Formula 2. Claims 13-21 and 24-25 are drawn to a method of treating a viral infection in a mammal comprising contacting a cell of the mammal with a compound according to Formula I or Formula 2.

SOMMADOSSI teaches compounds, methods and compositions of Formulae (II) and (V) for the treatment of hepatitis C infection (pages 7-11). The compounds include pharmaceutically acceptable salts and prodrugs. The instantly claimed compounds are embraced by the compounds of SOMMADOSSI. In a preferred embodiment, a compound of Formula (II) is provided wherein R^1, R^2 and R^3 are H; X^1 is H; X^2 is H or NH_2; and Y is hydrogen, bromo, chloro, fluoro, iodo, NH_2 or OH (page 23). In another preferred embodiment, a compound of Formula (V) is provided wherein R^1, R^2 and R^3 are H; X^1 is H or CH_3; and Y is hydrogen, bromo, chloro, iodo, NH_2 or OH (page 26). The compounds of SOMMADOSSI can be administered in combination or alternation with another anti-HCV agent (page 18). Examples of antiviral agents that can be used in combination with the disclosed compounds include an interferon and/or ribavirin.

SOMMADOSSI differs from the instant invention in that the compounds are described generically; however, the instantly claimed compounds would have been readily envisioned by one of ordinary skill in the art.

10. Claims 3-4, 7-8 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMADOSSI as applied to claims 1-2, 5-6, 9-21 and 24-25 above, and further in view of Erion et al. US 7,205,404 (Erion).

Although SOMMADOSSI teaches the use of prodrugs, SOMMADOSSI does not teach the instantly claimed cyclic phosphate, cyclic phosphonate or cyclic phosphoamidate. However, these deficiencies would have been obvious in view of the teachings of Erion.

Erion teaches novel prodrugs that generate phosph(on)ate compounds which are biologically active or are further phosphorylated to produce biologically active compounds (columns 1 and 5-7). A large class of drugs known to be active against hepatitis are generally nucleoside or nucleotide analogs that are phosphorylated inside cells to produce the biologically active triphosphate (column 4). Some specificity for virus-infected cells is gained by both preferential phosphorylation of the drug by virally-encoded kinases as well as by specific inhibition of viral DNA polymerases. The prodrugs are useful to treat diseases that benefit from enhanced drug distribution or specificity to the liver and like tissues and cells, including hepatitis (column 5).

Indeed it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the nucleoside compounds of SOMMADOSSI into a cyclic phosphate, cyclic phosphonate or cyclic phosphoamidate prodrug as

Erion teaches that such prodrugs are useful to treat diseases that benefit from enhanced drug distribution or specificity to the liver and like tissues and cells, including hepatitis.

Conclusion

11. Claims 1-25 are pending. Claims 1-25 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patrick T. Lewis/
Primary Examiner, Art Unit 1623

/PL/